

Remarks

Claim Status

Claims 1-42 were originally presented for examination in this application. An election of species requirement was issued on January 12, 2007, in response to which Applicants elected an evolutionary algorithm as recited in claims 2 and 23, proteins as the biological item being represented by the nodes as recited in claims 13 and 34, and medical data as the data representative of measured biological behavior or structures as recited in claims 19 and 40, leaving claims 1, 2, 4, 7-13, 15, 19, 21-23, 25, 28-34, 36, 40 and 42 for examination. An office action was issued on July 13, 2007, in which:

- Claims 1, 2, 4, 7-13, 15, 19, 21-23, 25, 28-34, 36 and 40 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Applicants have amended claims 1 and 22 to address this rejection.
- Claims 1, 2, 4, 7-13, 15, 19, 21-23, 25, 28-34, 36 and 40 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant's regard as the invention. Applicants have amended claims 1 and 22 to address this rejection.
- Claims 1, 2, 4, 7, 9-12, 15, 19, 21-23, 25, 28, 30-33, 36, 40 and 42 were rejected under 35 U.S.C. §103(a) as being obvious in light of Jeong et al. (Nature vol. 407 (2000) pp. 651-654), ("Jeong") and U.S. Patent Publication No. 2003/0224363 to Park et al. ("Park"). Applicants have amended claims 1 and 22 to address this rejection.
- Claims 8 and 29 were rejected under 35 U.S.C. §103(a) as being obvious in light of Jeong and Park in further in view of Barabasi et al. (Physica A, vol. 272 (1999) pp. 173-187) ("Barabasi").
- Claims 13 and 34 were rejected under 35 U.S.C. §103(a) as being obvious in light of Jeong and Park in further in view of Jeong et al. (Nature vol. 411 (2001) pg. 41), ("Jeong 2").

In this response, Applicants have amended claims 1 and 22 to address these rejections and to further clarify and describe the invention with greater particularity. Support for these

amendments can be found at least at paragraphs [0033] – [0034] of the application as published. No new matter has been added.

Claim Rejections Under 35 U.S.C. §101

Claims 1 and 22, as amended, both recite comparing proposed biological models to actual, measured data to determine a fitness score for each model, and, as a result, identifying one of the models as a previously-unrecognized but accurate representation of the biological system under study. Such a process is transformative by nature, in that creates new biological models and validates their accuracy with respect to real data. Further, creating such biological models produces a tangible result – a selected model that can then be used for numerous purposes, some examples of which include “drug discovery, patient data analysis, clinical data analysis, medicinal chemistry, and other applications” as described in the specification at paragraph [0034].

Claim Rejections Under 35 U.S.C. §103(a)

Independent claims 1 and 22, as amended, each recite selecting proposed biological models based on fitness measures of how the models compare to data representative of measured biological behavior or properties. Neither Jeong nor Park teach or suggest using a model-level fitness score to determine which model of a population of generated models is most accurate.

Briefly, Jeong describes a “comparative mathematical analysis of the metabolic networks of 43 organisms.” Jeong, pg. 651, Abstract. While Jeong may use conventional node and link-based methods for modeling metabolic networks, the purpose of such models is merely to allow for a mathematical analysis of topology of the networks in order to identify potential similarities among various organisms. As noted by the Examiner, Jeong does not teach assigning a fitness measure to the proposed biological models. For this element, the Examiner relies on Park.

Generally, Park describes data structures, methods and models for characterizing the *Bacillus subtilis* physiological function. Within a given model, Park describes a “metabolic database [that] can be annotated with a value indicating the confidence with which the reaction is believed to occur in *B. subtilis*.” Park, para. [0071]. Applicants respectfully disagree that applying a numerical probability to an individual reaction within a model (implying that there are many such annotations within a given model) anticipates or renders obvious the calculation of a

model-level fitness score that describes the ability of a model to accurately describe a complex biological function. Simply put, Park annotates individual reactions within a single model with confidence levels that supposedly reflect the degree to which a particular reaction actually occurs. Such confidence levels provide no insight into the accuracy of the model as a whole, and certainly do not facilitate the comparison of multiple models (as claimed in element (e)) to determine a preferred model for describing a biological function. It is this very point – the identification of one model (or, in some cases more than one model) out of a collection of many hypothesized models that may be used to simulate the actual biology of a specific system – that Park does not address, and proves invaluable for drug discovery.

Thus, because neither Jeong nor park teaches or suggests every element of independent claims 1 or 22 as amended, Applicants respectfully submit that these references, alone or in combination, fail to anticipate these claims or render the claims as obvious. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1 and 22 under 35 U.S.C. §103(a), as well as those claims that depend directly or indirectly therefrom.

Conclusion

Applicants respectfully submit that, in light of the foregoing amendments and remarks, claims 1, 2, 4, 7-13, 15, 19, 21-23, 25, 28-34, 36, 40 and 42 are in condition for allowance, and requests that application proceed to issue. If, in the Examiner's opinion, a telephonic interview would expedite the favorable prosecution of the present application, the undersigned attorney would welcome the opportunity to discuss any outstanding issues and to work with the Examiner toward placing the application in condition for allowance.

Respectfully submitted,

Date: February 12, 2008

Tel. No.: (617) 570-1057
Fax No.: (617) 523-1231

Electronic Signature: /Joel E. Lehrer/
Joel E. Lehrer, Reg. No. 56,401
Attorney for Applicants
Goodwin | Procter LLP
Exchange Place
53 State Street
Boston, Massachusetts 02109